UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,842	12/29/2005	Clara Lucia Garcia-Rodenas	112701-696	5990

29157 7590 11/18/2008

BELL, BOYD & LLOYD LLP
P.O. Box 1135
CHICAGO, IL 60690

EXAMINER	
WARE, DEBORAH K	

ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
11/18/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

Office Action Summary	Application No.	Applicant(s)	
	10/562,842	GARCIA-RODENAS ET AL.	
	Examiner	Art Unit	
	DEBBIE K. WARE	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 7-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-5 and 7-9 are pending.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on December 13, 2007, was filed and received. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Response to Amendment

The amendment filed July 21, 2008, and extension of time filed therewith, have been received and entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 1-5 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over previously cited Portman (US 6207638) in view of newly cited Mallee et al (US 6620778) and previously cited Kopf et al (6875459).

Claims are drawn to a method for preventing and/or improving metabolic conditions associated with Type 2 diabetes mellitus in a person comprising administering to the person a compostion comprising a protein source consisting essentially of intact whey proteins in an amount of 21 to 40 % dry wt or administering in an amount of 0.1 g intact whey proteins per kg body wt.

Portman teaches treating a person with type II diabetes comprising administering a nutritional composition comprising whey protein and casein and other ingredients.

Mallee et al teach that whey protein is an important cysteine source of which elevates glutathion levels in a person and glutathion plays a role in the prevention of cataracts, note col. 1, lines 30-35 and col. 4, line 35.

Kopf et al teach that a casein-depleted fraction containing whey proteins which contains soluble components for use in treating diabetes, note col. 7, lines 1-20.

The claims differ from Portman in that casein is not required by the claimed method and the active ingredient is intact whey protein.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to treat a person with type II diabetes administering a nutritional composition comprising whey protein as disclosed by Portman but in the absence of casein as disclosed by Mallee et al and Kopf et al in order to prevent or improve metabolic conditions associated with type 2 diabetes melitus in a person. Mallee et al clearly disclose that cysteine residues are comprised by whey protein and are useful for improving cataracts which are a condition associated with type II diabetes. One of ordinary skill in the art would have been motivated to increase the percentage by dry wt of a nutritional composition or dosage of Portman to enhance treatment of diabetes because Mallee et al and Kopf et al teach that whey proteins are useful. Mallee et al further explains that the cystiene residues are the active components in the whey which provide the expected successful result. One of skill would have been motivated to replace all of the casein in Portman with increased amounts of whey in view of the disclosures of Mallee et al and Kopf et al.

To optimize amounts to 0.1 to 0.8 g intact whey protein and/or to increase the amount of protein in the composition of Portman to a range of from 25 to 35% by wt is clearly within the skill of an ordinary artisan. Mallee et al clearly teach that at 20% is a desirable amount by weight. Sweet whey protein is well known and would have been an obvious modification of a nutritional supplement because it taste better than casein and would have been expected to provide successful results. The composition is disclosed to be in varied forms including a powder and to further include vitamins and other ingredients such as lecithin. The claims are prima facie obvious over the newly applied art rejection.

Response to Arguments

Applicant's arguments filed July 21, 2008, have been fully considered but they are not persuasive. The argument that each and every element is not disclosed is noted, however, no specific element has been referred to per se, however, if there is some element not specifically disclosed then it is considered to be at least suggested by the cited prior art. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., teachings in the specificaton at pages 4-5, lines 21-23 at page 4, and page 5 at lines 1-12, regarding post-prandial insulinemia and/or decreases of blood glucose levels, increases in amino acids, and example 1, etc.) are not recited in the rejected claim(s).

Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26

USPQ2d 1057 (Fed. Cir. 1993). The argument that Portman teaches casein and hence teaches away from the claimed invention is noted, however, Portman is combined with Mallee et al which clearly teaches the desire to not select for casein. Thus, to provide for a method of administering a composition consisting essentially of whey protein or intact whey protein is clearly suggested by the cited prior art combination. To select the total dry weight of the composition and dosage of 0.1 to 0.8 grams intact whey protein is also a matter of routine optimization of the amounts as disclosed by the cited prior art.

Further, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Also in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the previously enclosed PTO-1449 Form and/or PTO-892 Form. Therefore, the claims are properly rejected.

The remaining references cited on the previously enclosed Forms are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DKW/
Deborah K. Ware
Art Unit 1651

/David M. Naff/
Primary Examiner, Art Unit 1657